

## REMARKS

Claims 21-40 are pending. Claims 21, 28, 29, 34-38, and 40 are under examination, and claims 22-27, 30-33, and 39 are withdrawn as being directed to non-elected subject matter. Claims 28, 29, and 40 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form. Claims 21 and 34-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Stürzebecher et al., DE 10029014-A1 (“Stürzebecher”).

### *Claim Objections*

Claims 28, 29, and 40 are objected to as being dependent upon a rejected base claim. Claims 28 and 40 depend from claim 21, and claim 29 depends from claim 28. Based on the arguments presented herein, Applicants respectfully submit that claim 21 is in condition for allowance, and this ground for objection should be withdrawn.

### *Claim Rejection under 35 U.S.C. § 102(b)*

Claims 21 and 34-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stürzebecher. Applicants respectfully traverse this rejection.

M.P.E.P. § 2131 relates to the anticipation of claims by a prior art reference. This section clearly states that (emphasis added):

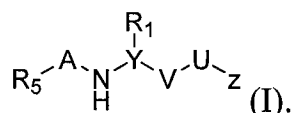
“[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, (Fed. Cir. 1987)).

Guidance relating to the anticipation of structures and compositions is also provided in M.P.E.P. § 2131 (emphasis added):

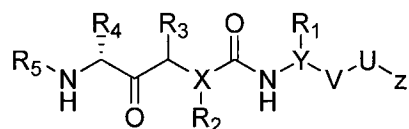
“[w]hen a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art” (citing *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001)).

For a claim to be anticipated under 35 U.S.C. § 102 by a prior art reference, the reference must teach a compound that falls within the claimed genus. Following the guidelines established in the M.P.E.P. and in the case law, Stürzebecher cannot anticipate any of instant claims 21 or 34-38.

Claim 21 recites compounds of general formula I, which has the following structure:



Formula I can also be described as follows:



The instant specification teaches that (emphasis added):

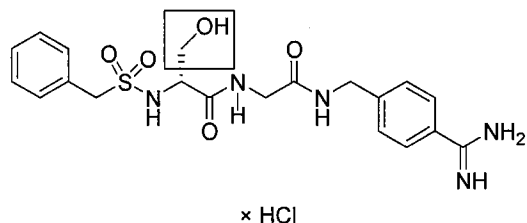
“[compounds of formula I that include] 4-amidinobenzylamine...both inhibit urokinase very effectively and are eliminated slowly from the circulation, in particular following i.v. or s.c. administration, when, in addition to the amidino function, other charged groups, preferably carboxyl, amino, amidino, hydroxyamidino, amidrazono or guanidino are introduced” (page 5, lines 17-24).

Accordingly, claim 21 further requires that the claimed compounds of formula I are:

“characterized in that one or more charged radicals, derived from  $-\text{COOH}$ ,  $-\text{CH}(\text{COOH})_2$ ,  $-\text{SO}_2\text{H}$ ,  $\text{NH}_2$ , an amidino, hydroxyamidino, amidrazono, or guanidino group, are present in the radicals  $\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$  or  $\text{R}_5$ ....”

Pursuant to the M.P.E.P. and the case law, any compound that is cited as anticipatory by the Office must be charged in the manner required by the claims, i.e., at least one of  $\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_3$ , or  $\text{R}_5$  must be charged.

In stating that Stürzebecher anticipates instant claims 21 and 34-38, the Office has cited the hydrochloride salt of benzylsulfonyl-D-Ser-Gly-amidinobenzylamide (“the Stürzebecher compound”). Analysis of the Stürzebecher compound and instant formula I shows the following correspondence:

**Stürzebecher compound:****Corresponding Groups in Instant Formula I:**

$R_1 = H$ ;  
 $R_2 = H$ ;  
 $R_3 = H$ ;  
 $R_4 = -(CH_2)_fOR_{11}$ , where  $f=1$  and  $R_{11}$  is H;  
 $R_5 = -SO_2R_{12}$ , where  $R_{12}$  = unsubstituted aralkyl;  
 $U$  = phenyl;  
 $V = (CH_2)_n$ , where  $n = 0$ ;  
 $X = CH$ ;  
 $Y = (CH_2)_m$ , where  $m = 1$ ; and  
 $Z$  = occurs in the 4-position and is an amidino group  $-C(NH)NHR_{14}$ , where  $R_{14}$  is H.

In accord with Applicants' analysis, the Office has acknowledged that the highlighted Stürzebecher  $-CH_2OH$  group is equivalent to  $R_4$  of instant formula I (see, for example, page 2 of the Office Action). As a monohydrochloride salt, the Stürzebecher compound bears only one positive charge. If the Stürzebecher  $-CH_2OH$  group bore that positive charge,  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_5$  must be uncharged. There is no legal basis for anticipation of the instant claims by a compound where  $R_4$  is charged and  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_5$  are not charged.

Further, for the record, Applicants respectfully disagree with the Office's assertion that the Stürzebecher  $-CH_2OH$  group, rather than the amidine group, is positively charged. The  $pK_a$  of an amidinium group is  $\sim 12-13$ , rendering this functional group a strong base. By contrast, the  $pK_a$  of a protonated alcohol  $ROH_2^+$  is  $\sim -2$ , rendering this functional group a strong acid. The amidine group is therefore  $\sim 10^{14}-10^{15}$  times more basic than the  $-CH_2OH$  group, and it is this functional group that is charged in the Stürzebecher compound. The Stürzebecher benzylamidinium group corresponds to substructure  $-Y(-R_1)-V-U-Z$  of instant formula I, and each of  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_5$  is therefore uncharged. Consequently, the Stürzebecher compound is not encompassed by the instant claims.

In further support of the arguments presented herein, Applicants attach a Declaration by Andrea Schweinitz, an inventor of both the instant application and Stürzebecher, attesting to the structural and chemical features of the Stürzebecher compound.

Claims 34 and 35 are directed to salts of the compound of claim 21. Claim 36 is directed to a method of preparing the compound of claim 21. Claims 37 and 38 are directed to pharmaceutical compositions that include the compound of claim 21. Because Stürzebecher does not anticipate claim 21, this reference similarly does not anticipate claims 34-38. Applicants respectfully request withdrawal of this ground for rejection.

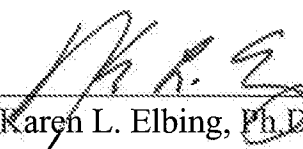
#### CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office action for two months, to and including June 30, 2009, and payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 30 June 2009

  
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